MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100788-PIP01-22

Scope of the Application

Active Substance(s)

favezelimab; PEMBROLIZUMAB

Condition(s)

Treatment of Hodgkin lymphoma

Pharmaceutical Form(s)

Concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Merck Sharp & Dohme (UK) Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Ltd submitted to the licensing authority on 12/12/2022 16:53 GMT an application for a Paediatric Investigation Plan

The procedure started on 27/03/2023 10:18 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan and grant a deferral and grant a waiver

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100788-PIP01-22

Of 15/06/2023 18:29 BST

On the adopted decision for favezelimab; PEMBROLIZUMAB (MHRA-100788-PIP01-22) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for favezelimab; PEMBROLIZUMAB, Concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Merck Sharp & Dohme (UK) Ltd, 120 Moorgate, London, UNITED KINGDOM, EC2M 6UR

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Hodgkin lymphoma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 3 years of age Pharmaceutical form(s): Concentrate for solution for infusion Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Hodgkin lymphoma

2.2 Indication(s) targeted by the PIP:

Treatment of relapsed or refractory classical Hodgkin lymphoma in paediatric patients from 3 years to less than 18 years of age. Treatment of newly diagnosed classical Hodgkin lymphoma in paediatric patients from 3 years to less than 18 years of age.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 3 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age appropriate formulation for the paediatric population in case the simulation analyses, and results of the clinical study 2 demonstration that the current ratio of favezelimab/ pembrolizumab (4:1) is not appropriate in children from 3 years to less than 12 years of age or a body weight $<$ 40/kg.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 Open-label single arm, multicentre study to evaluate the safety, pharmacokinetics (Part 1-run in phase) and the anti-tumour activity (part 2-expansion phase) of favezelimab/ pembrolizumab in paediatric patients from 3 years to less than 18 years of age with relapsed or refractory classical Hodgkin lymphoma. Study 3 Randomised, active controlled multicentre study to evaluate the safety, pharmacokinetics and efficacy of favezelimab/ pembrolizumab used in monotherapy or in combination with standard of care , compared to standard of care, in paediatric patients from 3 years to less than 18 years of age with newly diagnosed classical Hodgkin lymphoma. Study

		design and study population to be agreed by the Regulatory Agency based on the results of Study 2 prior to study initiation.
Extrapolation, Modeling & Simulation Studies	1	Extrapolation Plan Study 2 is part of the extrapolation plan of efficacy data from adults to children and adolescents from 3 years to less than 18 years of age with relapsed or refractory classical Hodgkin lymphoma.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/04/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes